Section 5 – 510(k) Summary or 510(k) Statement

K121150

SEP 21 2012

I. General Information

Submitter:

Alma Lasers, Inc.

485 Half Day Road Suite 100

Buffalo Grove IL 60089

Contact Person:

Kathy Maynor - Regulatory

352-586-3113 (cell)

Summary Preparation Date: June 28, 2012

II. Names

Device Name(s): Accent Pixel RF Tips

Primary Classification Name(s): Electrosurgical cutting and coagulation device and accessories

III. Predicate Devices

- Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (K072699, K070004, K101147)
- Syneron Medical Matrix RF Applicator (K073572, K090025)
- EndyMed RF Applicator (K083461, K101510, K120513)

IV. Product Description

The Accent Pixel RF Tips include cleanable, sterilizable, multiple use radiofrequency (RF) energy delivery devices (accessory) intended for use with the Alma Lasers Family of Accent™ RF Systems [Accent, Accent XL, Accent Elite]. These Pixel RF Tips are also available as single use, disposable products.

The Accent Pixel RF Tips are comprised of the following main components:

- Pixel^{RF} Stationary Tip
- Pixel^{RF} Roller Tip

V. Intended Use & Indications for Use

Intended Use

The Alma Lasers family of Accent RF Systems (Accent, Accent XL, Accent Elite) with Unipolar and Bipolar Handpieces are intended for use in dermatologic and general surgical procedures.

Indications for Use

The Unipolar and Bipolar handpieces, when used as a combined treatment, are indicated for the non-invasive treatment of wrinkles and rhytids.

The Pixel RF Tips (stationary and rolling), when used with the unipolar handpiece, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.

VI. Rationale for Substantial Equivalence

The Accent Pixel RF Tips shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices. Additionally, animal and human clinical data were submitted to substantiate product performance.

Characteristic	**K0XXXX** **Alma Lasers, Ltd.** **Family of Accent RF Pixel Tips with Pixel^{RF} Module/ Handpiece**	**K072699, K070004, K101147** Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (w/ UniPolar & BiPolar Handpieces]	**K073572, K090025** Syneron Medical Matrix RF Applicator	**K083461, K101510, K120513** EndyMed RF applicator
Product Code Regulation	General & Plastic Surgery • GEI, OUH – 21 CFR 878.4400	General & Plastic Surgery • NUV,GEI, ISA 21 CFR 878.4810	General & Plastic Surgery • GEI, OUH - 21 CFR 878.4400	General & Plastic Surgery GEI, OUH - 21 CFR 878.4400
Intended Use	Intended for use in dermatologic and general surgical procedures	Intended for use in dermatologic and general surgical procedures	Intended for use in dermatologic and general surgical procedures	Intended for use in dermatologic and general surgical procedures

K121150

Characteristic	**K0XXXX** **Alma Lasers, Ltd.** **Family of Accent RF Pixel Tips with Pixel^{RF} Module/ Handpiece**	**K072699, K070004, K101147** Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (w/ UniPolar & BiPolar Handpieces]	**K073572, K090025** Syneron Medical Matrix RF Applicator	**K083461, K101510, K120513** EndyMed RF applicator
Indications for Use	The Alma Lasers family of Accent RF Systems (Accent, Accent XL, Accent Elite) with Unipolar and Bipolar Handpieces are intended for use in dermatologic and general surgical procedures. The Unipolar and Bipolar handpieces, when used as a combined treatment, are indicated for the non-invasive treatment of wrinkles and rhytids. The Pixel RF Tips (stationary and rolling), when used with the unipolar handpiece, are indicated for dermatological procedures requiring ablation and resurfacing of the skin. **Supported by animal histology data – section 19 – and human clinical data – section 20.**	Indicated for: The non-invasive treatment of **wrinkles and rhytids** using a combined treatment with Unipolar and Bipolar handpieces	The Matrix RF Applicator is intended for dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles.	***The Glow by EndyMed*** is a noninvasive device intended for use in Dermatologic and General Surgical procedures.- The **TC** applicator is indicated for mild to moderate facial wrinkles and rhytides. The FSR applicator is indicated for Dermatological procedures requiring ablation and resurfacing of the skin.

K121150

Characteristic	**K0XXXX** **Alma Lasers, Ltd.** **Family of Accent RF Pixel Tips with Pixel^{RF} Module/ Handpiece**	**K072699, K070004, K101147** Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (w/ UniPolar & BiPolar Handpieces]	**K073572, K090025** Syneron Medical Matrix RF Applicator	**K083461, K101510, K120513** EndyMed RF applicator
RF Power (or Energy)	• UniPolar - **Recommended Range - Stationary Tips** 45-60 W - **Recommended Range - Roller Tips** 35-55 W - **Maximum for Accent System** Up to 200 W (2.08 W/mm^2) (Nominal 35-80 W - Pixel^{RF} Tips – range of 0.15 to 2.08 W/mm^2)	• UniPolar & UniLarge Up to 200 W (1.51 W/mm^2) (Nominal 120-140 W) • BiPolar & BiFolarS Up to 420 W (1.51 W/mm^2) (Nominal 250-290 W)	• Bipolar - Up to 25 Joules per cm^2 (Tunable SelectPulse™ fractional technology – 3 programs which emulate the tissue effects of common skin resurfacing fractional laser technologies)	• Bipolar up to 65 watts Up to 62mj/pin

K121150

Page 5 of 8

Characteristic	**K0XXXX** **Alma Lasers, Ltd.** **Family of Accent RF Pixel Tips with Pixel^{RF} Module/ Handpiece**	**K072699, K070004, K101147** Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (w/ UniPolar & BiPolar Handpieces]	**K073572, K090025** Syneron Medical Matrix RF Applicator	**K083461, K101510, K120513** EndyMed RF applicator
Tip Matrix	**Stationary Pixel^{RF} Tips** • ~ 110 Pixel points (1.0 pixels/mm^2) **Roller Pixel^{RF} Tips** • ~132 Pixel points per cm (1.3 pixels/mm^2)	Not applicable (K072699 & K070004)	64 Matrix Points – per pulse 0.4 points/mm^2	112 matrix spots (1.3 matrix spots/mm^2)
Treatment Area	• Stationary Pixel^{RF} Tips (Unipolar) 12 mm dia. • Roller Pixel^{RF} Tips (Unipolar) 10 x 22.7 mm circumference 'roller'	• UniPolar & UniLarge 13 to 19 mm dia. • BiPolarS & BiPolar 8.95 to 13 mm dia.	12 x 12 mm – disposable tip 'spot' size (unipolar)	10 x 15 mm
Handpiece Dimensions	Pixel^{RF} Handpiece - 160 x 155 mm	• UniPolar - 169 x 205 mm • BiPolar - 167 x 203 mm	5.9 x 6.3 inches (15 x 16 cm)	Unknown

K121150

Characteristic	**K0XXXX** **Alma Lasers, Ltd.** **Family of Accent RF Pixel Tips with Pixel^{RF} Module/ Handpiece**	**K072699, K070004, K101147** Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (w/ UniPolar & BiPolar Handpieces]	**K073572, K090025** Syneron Medical Matrix RF Applicator	**K083461, K101510, K120513** EndyMed RF applicator
Patient Contact Materials	• Stationary Pixel^{RF} Tips – Aluminum • Roller Pixel^{RF} Tips – Aluminum, Sapphire	Handpieces: • Anodized aluminum and Delrin plastic	Unknown	Unknown
How provided	**Disposable and Reusable Stationary & Roller Pixel^{RF} Tips**: • Reusable, cleanable, sterilizable Tips and disposable tips also available	Not applicable	**Disposable tip** – up to 125 pulses	**Disposable tip** – up to 300 pulses
Electrical Reqs	110–120 V; 50–60 Hz; 5A	110–120 V; 50–60 Hz; 5A	90 - 230 VAC, 50–60 Hz, 7.5A	100-230 VAC; 1-3 A; 50-60 Hz
System Dimensions (")	26 x 17 x 16 AccentXL; 21 x 17 x 38 Accent; 26 x 18 x 16 Accent Beauty	26 x 17 x 16 AccentXL 21 x 17 x 38 Accent	20.87 x 15.35 x 11.42 (Tabletop system)	115 x 30 x 19 cm; 45 x 12 x 7 in.
System Weight	110(XL);	55 lbs	15.4 lbs (7 kg)	33 kg; 72.5 lb.

K121150

Page 7 of 8

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Accent Pixel RF Tips are substantially equivalent to the predicate devices. Additionally, animal and human clinical data were submitted to substantiate performance.

VIII. Conclusion

The Accent Pixel RF Tips were found to be substantially equivalent to the predicate devices.

The Accent Pixel RF Tips share the identical indications for use, similar design features, and functional features with, and thus are substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Alma Lasers Incorporated
% Ms. Kathy Maynor
Regulatory Consultant
485 Half Day Road, Suite W No. 100
Buffalo Grove, Illinois 60089

SEP 21 2012

Re: K121150
Trade/Device Name: Pixel RF Tips
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accesories
Regulatory Class: Class II
Product Code: GEI
Dated: August 31, 2012
Received: September 11, 2012

Dear Ms. Maynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~K[illegible]~~ K121150

Device Name: Pixel RF Tips

Indications for Use:

Intended Use

The Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] is intended for use in dermatologic and general surgical procedures.

Indications for Use

The Unipolar and Bipolar handpieces, when used as a combined treatment, are indicated for the non-invasive treatment of wrinkles and rhytids.

The Pixel RF Tips (stationary and rolling), when used with the unipolar handpiece, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.

Neil R. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121150

Prescription Use ✓	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1